

Application Number 10/531069

Further to the Amendment and Response filed November 10, 2008

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**Amendments to the Claims:**

This listing of claims will replace all prior versions and listings of claims in the application.

**Listing of Claims:**

1. (Withdrawn – currently amended) A capsule comprising a tablet, granule or fine granule and a gel-forming polymer, wherein ~~the~~ a release of an active ingredient is controlled ~~and a gel-forming polymer~~.
2. (Withdrawn – currently amended) The capsule according to claim 1, wherein the release of the active ingredient is controlled by a release-controlled coating-layer formed on a core particle containing ~~an~~ the active ingredient.
3. (Withdrawn) The capsule according to claim 2, wherein the release-controlled coating-layer contains a pH-dependently soluble polymer.
4. (Withdrawn) The capsule according to claim 2, wherein the release-controlled coating-layer is a diffusion-controlled layer.
5. (Withdrawn – currently amended) The capsule according to claim 1, wherein the release of the active ingredient is controlled by dispersing ~~an~~ the active ingredient into a release-controlled matrix composing the tablet, granule or fine granule.
6. (Withdrawn – currently amended) The capsule according to claim 2, wherein the tablet, granule or fine granule in which the release of the active ingredient is controlled has a disintegrant layer containing disintegrant formed on the core particle containing ~~an~~ the active ingredient and ~~a~~ the release-controlled coating-layer formed on said disintegrant layer, and ~~the~~ a release of the active ingredient is initiated after a certain lag time.

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7. (Withdrawn – currently amended) The capsule according to claim 1, wherein the tablet, granule or fine granule in which the release of the active ingredient is controlled is coated with ~~a~~ the gel-forming polymer.

8. (Withdrawn) The capsule according to claim 7 which further contains a gel-forming polymer.

9. (Withdrawn – currently amended) The capsule according to claim 1, which comprises two kinds of tablet, granule or fine granule having different release properties of the active ingredient.

10. (Withdrawn – currently amended) The capsule according to claim 9, which comprises ~~a~~ the tablet, granule or fine granule having an enteric coat that releases ~~an~~ the active ingredient at the pH of about 5.5 and ~~a~~ the tablet, granule or fine granule having a release-controlled coating-layer that releases ~~an~~ the active ingredient at the pH of about 6.0 or above.

11. (Withdrawn) The capsule according to claim 1, 7 or 8, wherein the gel-forming polymer is a polymer whose viscosity of 5% aqueous solution is about 3,000 mPa·s or more at 25°C.

12. (Withdrawn) The capsule according to claim 1, 7 or 8, wherein the gel-forming polymer is a polymer having molecular weight of 400,000 to 10,000,000.

13. (Withdrawn) The capsule according to any one of claims 2 to 4 or 6, wherein the release-controlled coating-layer is a layer containing one or more kinds of polymeric substances selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, ethyl acrylate-methyl methacrylate-trimethylammoniummethyl methacrylate chloride

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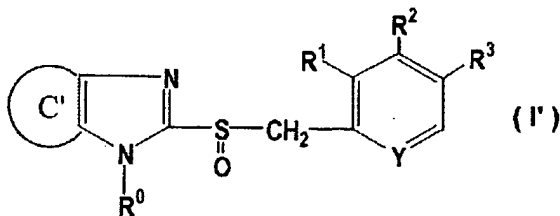
copolymer, methyl methacrylate-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate and polyvinyl acetate phthalate.

14. (Withdrawn – currently amended) The capsule according to claim 13, wherein the release-controlled coating-layer is comprised of 2 or more kinds of the layers.

15. (Withdrawn) The capsule according to claim 1, wherein the release-controlled granule or fine granule has a particle size of about 100-1,500  $\mu\text{m}$ .

16. (Withdrawn) The capsule according to claim 1, wherein the active ingredient is a proton pump inhibitor (PPI).

17. (Withdrawn – currently amended) The capsule according to claim 16, wherein the PPI is an imidazole compound represented by ~~the~~ formula (I'):



wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring,  $R^0$  is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group,  $R^1$ ,  $R^2$  and  $R^3$  are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom or CH; or a salt thereof or an optically active isomer thereof.

18. (Withdrawn) The capsule according to claim 17, wherein the imidazole compound is lansoprazole.

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19. (Withdrawn) The capsule according to claim 17, wherein PPI is an optically active R-isomer of lansoprazole.

20. (Withdrawn) The capsule according to any one of claim 1, 7 or 8, wherein the gel-forming polymer is one or more kinds of substances selected from the group consisting of polyethylene oxide (PEO, molecular weight: 400,000-10,000,000), hydroxypropylmethyl cellulose (HPMC), carboxymethyl cellulose (CMC-Na), hydroxypropyl cellulose (HPC), hydroxyethyl cellulose and carboxyvinyl polymer.

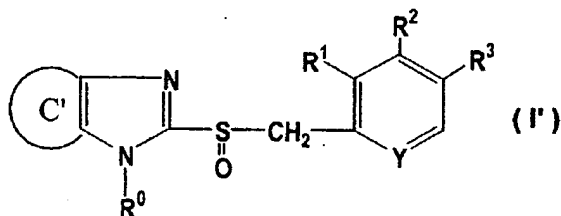
21. (Withdrawn) The capsule according to any one of claim 1, 7 or 8, wherein the gel-forming polymer is polyethylene oxide (molecular weight: 400,000-10,000,000).

22. (Withdrawn) The capsule according to claim 1, wherein the gel-forming polymer is added as a powder, fine granule or granule.

23. (Withdrawn) The capsule according to claim 3, wherein the pH-dependently soluble polymer is methyl methacrylate-methacrylic acid copolymer.

24. (Withdrawn – currently amended) A tablet, granule or fine granule wherein the a release of an active ingredient is controlled, said tablet, granule or fine granule comprising:

a core particle containing an imidazole compound represented by the formula (I'):



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wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring, R<sup>0</sup> is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom or CH; or a salt thereof or an optically active isomer thereof as ~~an~~ the active ingredient, and

a pH-dependently soluble release-controlled coating-layer which comprises one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac, and said polymeric substance is soluble in the pH range of 6.0 to 7.5 .

25. (Withdrawn – currently amended) The tablet, granule or fine granule according to claim 24, wherein the pH-dependently soluble release-controlled coating-layer is formed on an intermediate layer which is formed on ~~a~~ the core particle.

26. (Withdrawn – currently amended) ~~The A~~ capsule comprising the tablet, granule or fine granule according to claim 24.

27. (Withdrawn – currently amended) ~~The A~~ capsule comprising the tablet, granule or fine granule according to claim 24 and an enteric-coated tablet, granule or fine granule containing ~~a~~ the compound represented by ~~the~~ formula (I').

28. (Withdrawn) The tablet, granule or fine granule according to claim 24, wherein the active ingredient is lansoprazole.

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29. (Withdrawn) The tablet, granule or fine granule according to claim 24, wherein the active ingredient is an optically active R-isomer of lansoprazole.

30. (Withdrawn) The tablet, granule or fine granule according to claim 24, wherein the active ingredient is an optically active S-isomer of lansoprazole.

31. (Withdrawn) The tablet, granule or fine granule according to claim 24, wherein the active ingredient is a derivative of lansoprazole.

32. (Withdrawn) The tablet, granule or fine granule according to claim 24, wherein the active ingredient is a derivative of optically active R-isomer of lansoprazole.

33. (Withdrawn – currently amended) The tablet, granule or fine granule according to claim any one of 24, 25 or 28 to 32, comprising having an enteric coat on the core particle containing ~~an~~the active ingredient, a disintegrant layer containing disintegrant on said enteric coat and a release-controlled coating-layer on said disintegrant layer.

34. (Withdrawn) The tablet, granule or fine granule according to any one of claim 24, 25 or 28 to 32, which is coated with a gel-forming polymer.

35. (Withdrawn) An extended release capsule comprising the tablet, granule or fine granule according to any one of claim 28 to 32 and a gel-forming polymer.

36. (Withdrawn – currently amended) ~~A~~The tablet, granule or fine granule according to claim 24 wherein the release of the active ingredient is controlled by two or more kinds of the release-controlled coating-layers, and the outermost release-controlled coating-layer is soluble at higher pH than the inner release-controlled coating-layer.

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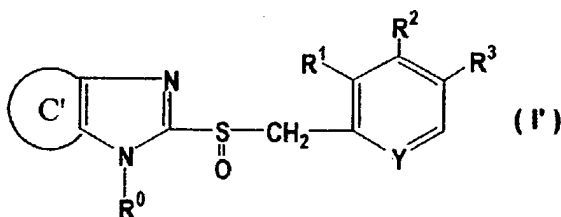
37. (Withdrawn) The tablet, granule or fine granule according to claim 36, wherein the inner release-controlled coating-layer is soluble in the pH range of 6.0-7.0 and the outermost release-controlled coating-layer is soluble at the pH of 7.0 or above.

38. (Withdrawn) The tablet, granule or fine granule according to claim 36, wherein the inner release-controlled coating-layer is soluble in the pH range of 6.5-7.0 and the outermost release-controlled coating-layer is soluble at the pH of 7.0 or above.

39. (Withdrawn – currently amended) The tablet, granule or fine granule according to claim 36, wherein the a thickness of the outermost release-controlled coating-layer is 100  $\mu\text{m}$  or less.

40. (Withdrawn) The granule or fine granule according to claim 36, wherein the release-controlled granule or fine granule has a particle size of about 100-1,500  $\mu\text{m}$ .

41. (Currently Amended) A capsule comprising:  
composition (i) comprising a tablet, granule or fine granule in which the a release of an active ingredient is controlled; said tablet, granule or fine granule comprises comprising a core particle containing an imidazole compound represented by the formula (I'):



wherein ring C' is an optionally substituted benzene ring or an optionally substituted aromatic monocyclic heterocyclic ring, R<sup>0</sup> is a hydrogen atom, an optionally substituted aralkyl group, acyl group or acyloxy group, R<sup>1</sup>, R<sup>2</sup> and R<sup>3</sup> are the same or different and are a hydrogen atom, an optionally substituted alkyl group, an optionally substituted alkoxy group or an optionally substituted amino group, and Y represents a nitrogen atom

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or CH; or a salt thereof or an optically active isomer thereof as ~~an~~the active ingredient, and

a pH-dependently soluble release-controlled coating-layer which comprises one kind of polymeric substance or a mixture of two or more kinds of polymeric substances having different release properties selected from the group consisting of hydroxypropylmethyl cellulose phthalate, cellulose acetate phthalate, carboxymethylethyl cellulose, methyl methacrylate-methacrylic acid copolymer, methacrylic acid-ethyl acrylate copolymer, methacrylic acid-methyl acrylate-methyl methacrylate copolymer, hydroxypropyl cellulose acetate succinate, polyvinyl acetate phthalate and shellac; said polymeric substance is soluble in the pH range of 6.0 to 7.5, and

composition (ii) comprising a tablet, granule or fine granule comprising a core particle containing ~~an~~the active ingredient and enteric coat ~~which is dissolved, thereby an~~ such that the active ingredient being is released in the pH range of no less than 5.0[[, ]] to no[[r]] more than 6.0.

42. (Currently Amended) The capsule according to claim 41, wherein the pH-dependently soluble release-controlled coating-layer is formed on an intermediate layer which is formed on the core particle containing ~~an~~the active ingredient.

43. (Original) The capsule according to claim 41, wherein the active ingredient is lansoprazole.

44. (Original) The capsule according to claim 41, wherein the active ingredient is an optically active R-isomer of lansoprazole.

45. (Original) The capsule according to claim 41, wherein the active ingredient is an optically active S-isomer of lansoprazole.

46. (Currently Amended) The capsule according to claim 41, wherein



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the core particles, which containing an the active ingredient and are included in the tablets, granules or fine granules of composition (i) and composition (ii), further contain[[s]] a stabilizer of basic inorganic salt stabilizer.

47. (Currently Amended) The capsule according to claim 41, wherein the pH-dependently soluble release-controlled coating-layer of the tablet, granule or fine granule in which the release of ~~an the~~ active ingredient is controlled is a layer soluble in the pH range of no less than 6.5[[, ]] ~~to no[[r]]~~ more than 7.0.

48. (Original) The capsule according to claim 47, wherein the pH-dependently soluble release-controlled coating-layer contains a mixture of two or more kinds of methyl methacrylate-methacrylic acid copolymers having different release properties.

49. (Original) The capsule according to claim 41, which further contains a gel-forming polymer.